



19th September, 2007

Dear Mr Feinmann

Re: Clinical and cost-effectiveness of continuous subcutaneous infusion for diabetes: updating review. Comments from the DAFNE (Dose Adjustment for Normal Eating) Executive.

Thank you very much for giving us the opportunity to comment on the above HTA document. I am responding on behalf of my colleagues in the UK DAFNE National Executive, who have read the report and had the chance to comment to me. I should declare that I was the Royal College of Physicians nominated member of the peer review panel, so I have made comments on an earlier draft to Prof Waugh in that capacity – I am now responding to the present document as the current Chairman of the DAFNE Executive.

DAFNE¹ (Dose Adjustment for Normal Eating), which is mentioned in the HTA, is a quality controlled, audited 5-day outpatient structured group education package for adult patients with Type 1 diabetes, which is now offered by 68 centres in the UK. The Scottish Executive has recently funded the training of 5 centres in Scotland. We have 6,430 DAFNE graduates in the programme at the time of writing.

DAFNE is based on a German model which has been reproduced in other European countries and has been cited as an exemplar for structured education by NICE and the NSF for diabetes. DAFNE and its parent programmes share the treatment goals of most intensified insulin therapy programmes (including pumps). These programmes are grounded in the educational principles that underpin successful insulin pump therapy, in particular the complete conceptual separation of basal insulin replacement and meal related insulin replacement. The education focuses on enabling the Type 1 patient to make regular and appropriate adjustments to insulin doses according to patterns of recent home blood glucose monitoring; variations in planned or recent exercise and alcohol intake and variations in meal timing and content. Patients learn accurately to assess the carbohydrate content of meals, so that their meal insulin doses are appropriate to freely-selected meals. The regimens use multiple daily injections of insulin (MDI), rather than pumps. As a group committed to the provision of effective adult education to support patient self management of insulin around flexible lifestyles, we would like to comment on the independent impact of such education on improved metabolic control and quality of life in Type 1 diabetes.

We endorse the HTA document from Prof Waugh's group. We agree that pumps can provide superior basal insulin delivery which may reduce hypoglycaemia compared to MDI and for some may simply be more convenient. The only major issue we would raise is that there is as yet no quantification of the added biomedical and quality of life benefits from pump therapy over skills training delivered in formal structured education programmes using MDI such as DAFNE. Such programmes can reduce HbA1c and severe hypoglycaemia and, as referred to in the HTA, also provide quality of life

improvements similar to those described for pump therapy (section 1.8). There has been no direct comparison of the magnitude of the biomedical and quality of life benefits of each approach.

We believe that skills training in insulin self-management is essential for the safe, cost effective use of pump therapy. We would like to underline the cost savings that should accrue for a pump programme, if the patients going onto pump have already completed an educational programme, such as DAFNE. Such a stepped approach may even limit the number of people wanting or needing to progress to pump therapy. It also recognizes that the technology does not of itself solve the problems of diabetes control and patients will need the skills of insulin self-adjustment to gain the benefits of the therapy. We strongly support the view that pump therapy needs to be supported by health care professionals experienced in intensified insulin usage and the delivery to users of appropriate diabetes self-management skills. The lack of benefit of pump therapy without such training has been evident from its early days.²

We welcome the conclusions of the HTA and the request for further trials to define the added benefit pump therapy may offer in specific patient groups. The DAFNE collaborative has an NIHR programme grant (Senior Investigator, Prof Simon Heller, Sheffield) to pilot a pump trial in the DAFNE setting, which will be done with a view to powering a fullscale trial using the MRC complex intervention methodology. We hope this may help to define the added benefit pump therapy may offer to a graduate of a programme such as DAFNE and whether such benefit would be universal.

Yours sincerely,

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References

1. DAFNE Study Group. Training in flexible, intensive insulin management to enable dietary freedom in people with type 1 diabetes: dose adjustment for normal eating (DAFNE) randomised controlled trial. *BMJ*. 2002;325(7367):746-50
2. Marshall SM, Home PD, Taylor R, Alberti KG. Abstract Continuous subcutaneous insulin infusion versus injection therapy: a randomized cross-over trial under usual diabetic clinic conditions. *Diabet Med*. 1987;4:521-5